Accompanying information for:

A global network for investigating the genomic epidemiology of malaria
The Malaria Genomic Epidemiology Network
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Further information at http://www.malariagen.net

JOINT POLICY ON DATA SHARING, INTELLECTUAL PROPERTY AND PUBLICATIONS

Defining terms

Consortium Project : A project using data and expertise from multiple investigators conducted with core MalariaGEN funds. This is agreed by the Project Management Committee and the funders as well as all the investigators taking part in the project.

Contributing Investigator : An investigator in MalariaGEN (included in the original grant proposal or invited to join by the Project Management Committee) contributing to a Consortium Project by submitting data and/or samples and expertise.

Investigator's own analysis : The results of an individual collaborator or small group of collaborators' project that are in some way facilitated by MalariaGEN. This may be through:

a) Use of genotyping data generated on samples contributed to Consortium Projects in conjunction with the collaborator's own non-Consortium data

b) Use of MalariaGEN funds to support generation of samples and clinical data in conjunction with the collaborator's own non-Consortium data

c) A more tangential relationship : use of publicly available Consortium genotyping resources, or published Consortium papers.

Key principles

1. 'Sovereignty of physical samples and clinical data contributed to the Consortium Projects remains with the contributing investigator'

This means:

- Physical DNA samples can only be used by the Consortium as follows:
    - For Consortium Projects of MalariaGEN
    - and, in addition only with the permission of the contributing investigator
    - and in addition only with national legal and ethical approval in the country of origin and in the country where the experiment takes place
- The Contributing Investigator is responsible for ensuring:
    - Appropriate informed consent is available for the experiments used
    - Appropriate legal and ethical approval is obtained
- The location of genotyping / analysis is responsible for:

    - The physical safety and integrity of the samples, as well as maintaining security and confidentiality of information on behalf of the contributing investigator

- The Contributing Investigator can:

    - Recall the physical samples at any stage after the agreed experiments have taken place

    - Use the samples for other additional purposes outside MalariaGEN

    - Release the samples to the Consortium for an agreed period of time only (particularly if constrained by national guidelines)

2. 'Genotype and specific phenotype data is only available for consortium experiments and the contributing investigator in the first instance'

This means:

- Genotyping data generated from samples by the Consortium Projects, and phenotype data recorded for and contributed to the Consortium Projects as part of sub-grants is automatically contributed to agreed consortium experiment for further analysis

- Genotyping data generated from samples by the Consortium Experiment is automatically returned to the Contributing Investigator

3. 'Consortium Project results are made public unless they are being considered for IP protection'

This means:

- They will be made available in draft to all investigators contributing data or expertise in the consortium experiment prior to publication

- They will be made available to all MalariaGEN investigators once manuscript is in press

- They will be made publicly available on the website after publication

- The project management committee must investigate whether pursuing IP protection is an important option prior to publication (according to principle 8)

4. 'Investigators' own analyses will not be affected by the publications policy but will be cited on the MalariaGEN web-site after publication'

This means:

- The results of investigator's own analysis will be published according to the wishes of the investigators.

In addition:

- The Consortium will develop an acceptable policy for highlighting prospective results to build synergy across the consortium and encourage 'peer advice'

However:

- Projects receiving funding from Grand Challenges must observe the terms and conditions of the Framework Agreement document in regard to guidelines for pursuing IP appropriately

5. 'Authorship of Consortium Publications will reflect the genuine contributions of MalariaGEN collaborators in accordance with normal academic practice'

Two types of consortium publications are envisaged:

- Whole Consortium publications: include the names of all MalariaGEN investigators and the names of their affiliation. The first 'Project Description' paper will be a MalariaGEN 'whole consortium publication'; as will other papers that relate to the workings of the group as a whole. This paper will be circulated prior to publication for review and comment. In addition, significant contributions will be recognized by naming individuals as authors (and could be external to MalariaGEN).
- Consortium Subgroup publications: Results of Consortium Projects will cite the name and affiliation of each member of MalariaGEN that contributes data or expertise to the publication. Additional names may be appropriate and details of authorship will be decided by a 'writing committee' established for each publication

6. 'The Consortium will wherever possible feed back results of scientific discovery to participating communities'

- Feedback and presentation of research progress and research results to participating communities in Malaria endemic countries is encouraged

7. 'The decision to patent before publishing results is taken by the Project Management committee for Consortium Projects and by individual investigators for their own analyses'

However:

- All funded projects by the Grand Challenges programme must adhere to the guidelines for pursuing IP in accordance with the Framework Agreement

8. 'All results will be released directly into the public domain via publication and then the web-site unless IP protection is necessary to enhance technology transfer to developing countries'

IP protection should be sought when:

- Discovery is directly relevant to clinical application (diagnostic, drug, or vaccine)
- And: Highly likely to be immediately licensed out
- And: Shown to require IP protection as a stimulus for further development

9. 'In the unlikely event of royalties flowing from IP licenses, mechanisms will be sought to ensure that they flow to the appropriate participating communities, and not to investigators'

10. 'Patents will be licensed to non-profit organisations – except where a for-profit company is able to dedicate significantly more resources, however in this case steps will be taken to ensure global access is achieved